



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,320	02/07/2002	Russell Mumper	NANO:002USD1	5127

7590 05/01/2009
David L. Parker, Esq.
FULBRIGHT & JAWORSKI L.L.P.
Suite 2400
600 Congress Avenue
Austin, TX 78701

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
----------	--------------

1618

MAIL DATE	DELIVERY MODE
-----------	---------------

05/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/072,320	Applicant(s) MUMPER ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-57 is/are pending in the application.
- 4a) Of the above claim(s) 48-50 and 52-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-47, 51, 56 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendments to the claims filed 03/23/2009 have been entered.

Specification

The amendment filed 03/23/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amounts of Noveon present in amounts of 33 to 80 wt% and Eudragit present in amounts from 20 to 67 wt%. While applicants have support for specific data points in table 1 such as a ratio of Noveon/Eudragit of 1:2, 2:2, 2:1, 3:1 and 4:1, this small subset of values does not give support for all possible ratios or when converted to percents, all amounts of Noveon and Eudragit now recited within the specification. Furthermore it is noted by the examiner that the above ratios were only expressed for Noveon/Eudragit alone, while applicants are reciting the amount of Noveon and Eudragit in the entire mucoadhesive layer.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

Art Unit: 1618

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As described above in the objection to the specification applicants do not have support within the specification to claim the amounts of Noveon and Eudragit now recited.

Response to Arguments

Applicant's arguments with respect to claims 33-47,51 and 56-57 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33-47,51 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle et al. (US 6,562,363 B1) in view of Suzuki et al. (US 4,715,369). This new rejection was necessitated by applicant's amendments to the claims.

Mantelle discloses a bioadhesive composition containing a bioadhesive layer with a backing layer, the bioadhesive layer contained 20 to 50 wt% of polyvinyl pyrrolidone (PVP), 5 to 50 wt% preferably 20 to 30 wt % of a bioadhesive including Noveon, an active agent including numerous types of peptides and 20 to 40 wt% of a pressure sensitive adhesive including commercially available Eudragit polymers (same as applicants claimed film-forming polymer). See abstract, claims, col 3 lin 39-41, col 5 lin 22-26, col 6 lin 5-23, col 8 lin 49-57, col 13 lin 26-35, col 36 lin 35-44, col 36 lin 66-

Art Unit: 1618

col 38 lin 25 and col 39 lin 54-col 40 lin 5. The bioadhesives could be administered to mucous membranes including oral and nasal administration. See col 6 lin 57-65. The thickness of the backing layer was generally in the range of 2 to 1000 micrometers and the thickness of the bioadhesive composition was from about 12 to 250 micrometers, if these two layers are added together the thickest film would at most be 1250 micrometers or 1.25 mm, less than applicants claimed thickness of 5 mm. See col 40 lin 6-20.

Mantelle while disclosing the use of a backing layer is silent on the use of a wax backing layer as required in applicants claims.

Suzuki is cited in the previous office action filed 12/23/2008 and is used primarily for the disclosure within that wax was a well known backing material for use in mucosa adhesives at the time of applicants claimed invention.

Since both references are related to the same general field of endeavor, oral mucosa adhesives, one of ordinary skill in the art would have a high expectation of success in modifying the backing layer disclosed in Mantelle and adding the wax backing layer disclosed within Suzuki. It is generally considered to be prime facie obvious to combine or substitute materials each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, the instant claims are no more than the combination of conventional components of mucosa adhesive patches.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

Art Unit: 1618

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618